Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association

Draft Guidance

This guidance document is being distributed for comment purposes only.

Draft released for comment on November 22, 2004.

Comments and suggestions regarding this draft document should be submitted within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with Docket Number 2004D-0510. For questions regarding this draft document contact Tim Hansen, Center for Food Safety and Applied Nutrition (CFSAN), (301) 436-1405.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Seafood
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This draft Level One guidance represents FDA's current thinking on Certification of Fishery Products for Export to the European Union and the European Free Trade Association. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations. The draft guidance is being distributed for comment purposes in accordance with FDA's Good Guidance Practices (21 CFR 10.115; September 19, 2000).

I. EU Export Health Certificate Protocol Referral Program

Purpose

Since 1993, the European Union (EU) has required that EU Export Health Certificates (EU Export Certificates) accompany all shipments of fish and fishery products that are shipped to the EU. The Food and Drug Administration (FDA or agency), as the sole food safety regulatory authority for commercial fish and fishery products at the United States federal level, is the primary competent authority in the U.S. responsible for the issuance of these certificates. In 1993, to ensure the smooth flow of trade in fish and fishery products to the EU, FDA voluntarily began signing certificates, free of charge, for shipments of fish and fishery products to the EU. The FDA also signs certificates for shipments of fish and fishery products to EU Accession Partnership Countries, and members of the European Free Trade Association (EFTA). FDA's expectation at that time was that its role in providing these certificates would be temporary (see *Draft Guidance on Equivalence Criteria for Food* [62 FR 30593], June 4 1997). This expectation was further supported by the ability of seafood processors to obtain EU Export Certificates elsewhere. Under the provisions of the Agricultural Marketing Act (AMA), the Seafood Inspection Program of the National Oceanic and Atmospheric Administration (NOAA SIP) of the Department of Commerce also signs EU Export Certificates on a fee-for-service basis that are accepted by EU authorities.

The demand for EU Export Certificates by industry has risen dramatically in recent years and has caused significant resource allocation problems for FDA. The diversion of resources to lower priority, discretionary activities diminishes the agency's ability to carry out public health activities and regulatory oversight that are intended to protect the U.S. consuming public. While this has been true for some time, after the terrorist acts of September 11, 2001, the need to focus on food defense makes it harder to justify the use of FDA resources for issuance of such certificates, particularly when another agency is issuing these certificates. The increased demand, in combination with limited FDA resources, creates a particular problem for live and perishable fish and fishery products whose value depends on prompt exportation.

In order to expedite the exportation of live and perishable fish and fishery products, FDA is considering what parts of its current EU certification activities related to fish and fishery products could be conducted by NOAA SIP. FDA is, therefore, proposing to operate a Referral Program for a 24-month period to test the viability and effectiveness of such an arrangement. During this period, EU Export Certificates for all shipments of live and perishable fish and fishery products destined for the EU, EU Accession Partnership Countries, and EFTA Members would be issued by the NOAA SIP under the Agricultural Marketing Act. The basis for issuing EU Export Certificates under the Referral Program would be whether the establishment or establishments in question are in regulatory good standing with FDA. This service is offered by NOAA SIP nationwide for a fee that provides for cost recovery. FDA intends to cease to issue EU Export Certificates for live and perishable fish and fishery products. During this period, both agencies intend to continue to issue EU Export Certificates for shipments of canned, frozen, dried, vacuum packed, etc. products, as requested by appropriate parties.

II. Agency Roles

The intended roles for each agency are delineated below.

A. FDA intends to:

1. Continue to serve as the primary competent authority for all EU-related Export Certificate services for fish and fishery products covered by this Referral Program. In that capacity, FDA intends to provide guidance and oversight to the NOAA SIP with regard to EU-related Export Certificates issued under this Referral Program.

2. Perform all of the roles and functions specified in the FDA document entitled "Guidance and Protocol for Industry and Food and Drug Administration Staff: Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association" (FDA Protocol). Those roles and

functions include, among other things: (a) establishing criteria, based on regulatory status, for determining whether U.S. establishments are eligible to receive EU Export Certificates based on whether the establishments are in regulatory good standing with FDA; (b) maintaining an up-to-date database on the current regulatory status of establishments (EU Export Certificate Lists); and (c) ensuring that the information from (a) and (b) is available to the NOAA SIP so that it has the ability to issue EU Export Certificates under this Referral Program.

3. Continue to provide EU Export Certificate services for shipments of fish and fishery products destined for the EU and EU Accession Partnership Countries, and EFTA Members that are frozen, canned, dried, vacuum packed, etc.

B. NOAA SIP intends to:

1. Issue requested EU Export Certificates on a fee-for-service basis to establishments for shipments of live and perishable fish and fishery products destined for the EU, EU Accession Partnership Countries, and EFTA Members in accordance with this Referral Program and the FDA "Guidance and Protocol for Industry and Food and Drug Adminstration Staff: Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association." For EU Accession Countries and EFTA Members, the certificates should also be issued in accordance with additional guidance that is on FDA's Center for Food Safety and Applied Nutrition website at www.cfsan.fda.gov/~dms/eucert.html.

2. For establishments seeking EU certification under pre-existing NOAA programs (i.e., non-Referral Program EU Export Certificates), continue to provide EU certification services for shipments of all fish and fishery products destined for the EU and EU Accession Partnership Countries.

3. For establishments seeking certification from NOAA SIP but that have not applied for inclusion on FDA's EU Export Certificate Lists, provide the establishment with FDA's guidance for entry onto the lists.

4. Provide initial point of contact with Department of Commerce Fishery Trade Specialist in Brussels and Paris. This contact will communicate Directives issued and policy decisions made by the EU to interested parties; notice of detention of U.S. products and other regulatory problems to the certifying agency; and inquiries from the U.S. seafood industry to EU officials.

5. Provide information to FDA whenever NOAA SIP has information from inspection or otherwise that an establishment seeking certification under this referral program should no longer be in regulatory good standing with FDA, e.g., where NOAA SIP has reason to believe that conditions in the establishment have deteriorated substantially since the most recent FDA inspection.

III. Guidance to Industry for Obtaining EU Export Certificates from NOAA SIP

1. An establishment seeking EU certification should contact the nearest inspection office maintained by NOAA SIP. See the appendix to this document for a list of NOAA SIP offices and contacts.

2. Applicants may request additional services from NOAA SIP in accordance with regulations governing processed fishery products (50 CFR 260) and guidelines related to these regulations.

IV. FDA Internal Audit Procedures

The NOAA SIP should be evaluated periodically by FDA in accordance with appropriate quality auditing principles to determine that the certificate process is carried out in an effective manner.

Interested persons may submit written comments on the draft guidance within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Dockets Management Branch (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with Docket Number 2004D-0510. Submit electronic comments on the draft guidance to http://www.fda.gov/dockets/ecomments. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 2004

Appendix:

LIST OF CONTACTS FOR NOAA SIP FOR EU CERTIFICATION

Dr. Kenneth Aadsen
Chief, Technical Services Branch
NOAA Seafood Inspection Program
1315 East-West Highway
Silver Spring, MD 20910
Telephone: 301-713-2355
Fax: 301-713-1081

Northeast Inspection Branch
11-15 Parker Street - Room 213
Gloucester, MA 10930
Telephone: 978-281-9228
Fax: 978-281-9134

Southeast Inspection Branch
9721 Executive Center Drive N., Suite 133
Koger Building
St. Petersburg, FL 33702
Telephone: 727-570-5383
Fax: 727-570-5387

Western Inspection Branch
7600 Sand Point Way, N.E.
Bldg 32, Room 286A
Seattle, WA 98115
Telephone: 206 526-4259
Fax: 206 526-4265

A more complete list of contacts and offices may be found on the NOAA SIP homepage at http://seafood.nmfs.noaa.gov/.